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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,632	11/17/2003	Michael E. Mendelsohn	00398/518002	4319
21559	7590	11/04/2004	EXAMINER	
CLARK & ELBING LLP 101 FEDERAL STREET BOSTON, MA 02110			GEBREYESUS, KAGNEW H	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 11/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/715,632	Applicant(s) MENDELSON ET AL.	
	Examiner Kagnew H Gebreyesus	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) 1-4 and 10-35 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 5-9 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some c) ☒ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

1. Claims 1-4 and 10-35 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected group there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 10/06/2004.

Claim Objections

2. Claims 5 and 6 are objected to because of the following informalities: It is advisable to avoid using an abbreviation for myosin phosphatase-Rho interacting protein in the beginning claims. Appropriate correction is required.

Priority

3. Applicant's claim for priority under 119(e) is acknowledged. However, provisional application (60/426,591) filed on Nov./17/2002 does not disclose the nucleic acid sequence currently claimed. Therefore the benefit of the filing date of the priority document i.e. of Nov. 17/2002 is not accorded.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 5 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim

5 is drawn to a nucleic acid sequence with at least 90% identity to SEQ ID NO: 19. The specification does not contain a disclosure of the function of all polynucleotides having 90% identity to SEQ ID NO: 19. The genus of nucleic acids claimed is a large variable genus with the potentiality of encoding many different proteins. Therefore many functionally unrelated nucleic acids are encompassed within the scope of the claimed genus. The specification discloses only a single species of the claimed genus which is insufficient to put one of skill in the art in possession of the attribute and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed. Applicant is referred to the revised interim guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 5, 6 and 9 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Claims 5, 6 and 9 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a myosin phosphatase-Rho interacting protein (M-RIP) gene having SEQ ID NO: 19 which encodes for a polypeptide of SEQ ID NO: 1, does not reasonably provide enablement for any M-RIP gene having 90% identity to the polynucleotide of SEQ ID NO: 19. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate with the enablement provided by the disclosure

with regard to the extremely large number of nucleic acids encoding human M-RIP broadly encompassed by the claims. Since the amino acid sequence of a protein encoded by a nucleic acid determines its structural and functional properties, predictability of which changes in a nucleic acid sequence can be tolerated in a protein's amino acid sequence and obtain the desired activity requires a knowledge of and guidance with regard to which nucleotide in the DNA sequence, if any, are tolerant of modification and which are conserved (i.e. expectedly intolerant to modification), and detailed knowledge of the ways in which the DNA structure relates to the function of the protein encoded by the same. However, in this case the disclosure is limited to SEQ ID NO: 19 encoding the protein of SEQ ID NO: 1. Claims 5, 6 and 9 are so broad as to encompass any M-RIP having 90% identity to SEQ ID NO: 19. These claims are directed to a genus of DNA molecules with either SEQ ID NO: 19 or DNA having the limitations of encoding a protein having the SEQ ID NO: 1 or any DNA which is 90% identical to SEQ ID NO:19.

The scope of the claims is not commensurate with the enablement provided by the disclosure with regard to the potentially large number of M-RIP genes broadly encompassed by the claims because the specification does not establish: (A) regions of the DNA structure with 10% sequence diverge without effecting the activity of the protein encoded by it; (B) the general tolerance of the gene to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying the nucleic acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope

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of the claims broadly including a nucleic acid molecule having less than 100% sequence identity SEQ ID NO: 19 or to the human M-RIP gene. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of an M-RIP gene having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

Claim 5-9 are rejected under 35 U.S.C. 102(a) as being anticipated by applicant's published disclosure in electronic format on 23/ Sep. /2003 in the J. Biol. Chem. 278 (51) 51484-51493 (2003).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

In addition claims 5, 6 and 9 are rejected as being anticipated by Inazawa et al. who cloned and sequenced a human gene encoding a RhoA-interacting protein-3.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 5, 6 and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by GeneBank Accession No. AL834513. GeneBank Accession No. AL834513 teaches a nucleic acid having 96.1% identity to SEQ ID NO: 19. This gene is identified as a gene encoding a human RhoA-binding protein showing a strong similarity to p116Rip from *Mus musculus*. Thus this gene anticipates all of claims 5, 6 and 9.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. In addition claim 5 is rejected under 35 U.S.C. 102(e) as being anticipated by WO 2003031568-A2 with a published provisional application with a priority filing date of 14/Sep./2001. WO 2003031568-A2 discloses a sequence having 99.7% sequence identity to SEQ ID NO: 19 encoding a human intracellular signaling molecule.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kagnew H Gebreyesus whose telephone number is 571-272-2937. The examiner can normally be reached on 8:30 am-5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Achutamurthy ponnathapura can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Kagnew Gebreyesus PhD.

E. Slobodyansky
ELIZABETH SLOBODYANSKY, PH.D
PRIMARY EXAMINER